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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/554,604	05/31/2000	Andrew J. Dannenberg	CRF D-2165	9421

7590

11/15/2001

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EXAMINER

WANG, SHENGJUN

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 11/15/2001

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/554,604

Applicant(s)

DANNENBERG, ANDREW J.

Examiner

Shengjun Wang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 September 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 7-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

1. Claims 7-16 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Applicant timely traversed the restriction (election) requirement in Paper No. 7, submitted September 6, 2001.

2. Applicant's election with traverse of Invention Group I, claims 1-6 in Paper No. 7, submitted September 6, 2001 is acknowledged. The traversal is on the ground(s) that all three groups should have the same area of search. This is not found persuasive because method of group II involves employments of combination of two active agents. Therefore the search of group II is not required in the search of group I.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections 35 U.S.C. 112

Claim 6 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for particular compounds as defined in page 18 in the specification, does not reasonably provide enablement for other agents which may be cox-2 inhibitor and also inhibits the synthesis of cyclooxygenase-2 protein. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Applicant uses functional limitation "inhibitor of cyclooxygenase-2 directly inhibits the enzyme cyclooxygenase -2 and also inhibits the synthesis of cyclooxygenase -2 protein" to define the agents employed in the method. A person of ordinary skill in the art would have been required to perform undue experimentation to use claimed invention, particularly, to identify those 'inhibitor of cyclooxygenase-2 directly

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inhibits the enzyme cyclooxygenase -2 and also inhibits the synthesis of cyclooxygenase -2 protein' within claimed scope. Attention is directed to *General Electric Company v. Wabash Appliance Corporation et al* 37 USPQ 466 (US 1938), at 469, speaking to functional language at the point of novelty as herein employed: the vice of a functional claim exists not only when a claims is wholly functional, if that is ever true, but when the inventor is painstaking when he recites what has already been seen, and then uses conveniently functional language at the exact point of novelty. Functional language at the point of novelty, as herein employed by Applicants, is further admonished in *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398 (CAFC 1997) at 1406: stating this usage does little more than outlin[e] goals appellants hope the recited invention achieves and the problems the invention will hopefully ameliorate. Applicants functional language at the point of novelty fails to meet the requirements set forth under 35 USC 112, first or second paragraph. Claims employing functional language at the point of novelty, such as Applicants, neither provide those elements required to practice the inventions, nor inform the public during the life of the patent of the limits of the monopoly asserted *General Electric Company v. Wabash Appliance Corporation et supra*, at 468.

Claim Rejections 35 U.S.C. 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

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4. Claims 1-5 are rejected under 35 U.S.C. 102(e) as being anticipated by Gregory et al. (US Patent 6, 172,096).

5. Gregory et al. teaches a method for treating a patient with organ transplantation comprising administering to the patient a cyclooxygenase-2 inhibitor employed herein. The transplantation includes liver, heart, and kidney. See, particularly, the claims, and column 5, lines 48-50.

Claim Rejections 35 U.S.C. 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gregory et al. (US Patent 6, 172,096), in further view of Tally et al. (US Patent 5,643,933, IDS).

8. Gregory et al. teaches a method for treating a patient with organ transplantation comprising administering to the patient a cyclooxygenase-2 inhibitor employed herein. The transplantation includes liver, heart, and kidney. See, particularly, the claims, and column 5, lines 48-50. Gregory et al. further teaches that the method is generally known to be useful for treating immune related disease including biliary cirrhosis. See, column 5, lines 42 bridging column 6, line 16.

9. Gregory et al. does not teach expressly the treatment of liver disease by the method therein.

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1. However, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed invention was made, to employ the method of Gregory for treating liver disease such as liver transplantation or biliary cirrhosis because this method are known to be useful for treating such disease. Regarding claim 6, which define the cox-2 inhibitor also inhibits the synthesis of cox-2 protein, note it is well settled patent law that mode of action elucidation does not impart patentable moment to otherwise old and obvious subject matter. Applicant's attention is directed to *In re Swinehart*, (169 USPQ 226 at 229) where the Court of Customs and Patent Appeals stated "is elementary that the mere recitation of a newly discovered function or property, inherently possessed by thing in the prior art, does not cause a claim drawn to those things to distinguish over the prior art." Additionally, where the patent Office has reason to believe that a functionally limitation asserted to be critical for establishing novelty in the claimed subject matter may, in fact, be an inherent characteristic of the prior art, it possesses the authority to requires the applicant to prove that the subject matter shown to be in the prior art does not posses the characteristic relied on. In the instant invention, the claims are directed to the ultimate utility set forth in the prior art, albeit distanced by various biochemical intertmediates. The ultimate utility for the claimed compounds is old and well known rendering the claimed subject matter obvious to the skilled artisan. It would follow therefore that the instant claims are properly rejected under 35 USC 103. Further, claim 6 is obvious for reasons discussed above, in further view of Tally. Tally teaches that the agent employed in claim 6, is known to be similarly useful as the compounds employed in claims 4 and 5, i.e., as cox-2 inhibitor. See, particularly, column 2, line 15 bridging column 3, line 25.

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10. Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tally et al. (US Patent 5,643,933), in further view of Tally et al. (US Patent 5,643,933, IDS).

11. Tally et al. ('933) teaches a method for treating inflammation or inflammation-associated disorder comprising administering to the subject in need the compounds employed herein. See, particularly, the abstract, column 18, lines 37-67, and claim 11.

12. Tally et al. does not teaches expressly to employ the compounds herein for treating liver disease.

2. However, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to employ the compounds for treating liver disease associated with inflammation, such as hepatitis because the compounds are known to be useful for treating inflammation associated disorder and hepatitis is well-known in the art to be associated with inflammation. Regarding claim 6, which define the cox-2 inhibitor also inhibits the synthesis of cox-2 protein, note it is well settled patent law that mode of action elucidation does not impart patentable moment to otherwise old and obvious subject matter. Applicant's attention is directed to In re Swinehart, (169 USPQ 226 at 229) where the Court of Customs and Patent Appeals stated "is elementary that the mere recitation of a newly discovered function or property, inherently possessed by thing in the prior art, does not cause a claim drawn to those things to distinguish over the prior art." Additionally, where the patent Office has reason to believe that a functionally limitation asserted to be critical for establishing novelty in the claimed subject matter may, in fact, be an inherent characteristic of the prior art, it possesses the authority to requires the applicant to prove that the subject matter shown to be in the prior art does not posses the characteristic relied on. In the instant invention, the claims are directed to the ultimate

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utility set forth in the prior art, albeit distanced by various biochemical intermediates. The ultimate utility for the claimed compounds is old and well known rendering the claimed subject matter obvious to the skilled artisan. It would follow therefore that the instant claims are properly rejected under 35 USC 103. Further, claim 6 is obvious for reasons discussed above, in further view of Tally. Tally teaches that the agent employed in claim 6, is known to be similarly useful as the compounds employed in claims 4 and 5, i.e., as cox-2 inhibitor. See, particularly, column 2, line 15 bridging column 3, line 25.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang, Ph.D. whose telephone number is (703) 308-4554. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

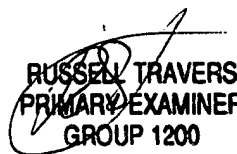
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.



Shengjun Wang

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November 10, 2001



RUSSEL TRAVERS
PRIMARY EXAMINER
GROUP 1200